

**510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Osteonics® Offset Hip Stem Series**

Submission Information

**Name and Address of the Sponsor
of the 510(k) Submission:**

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Contact Person:

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Device Identification

Proprietary Name:

Osteonics® Offset Hip Stem Series

Common Name:

Artificial Hip Component

Classification Name and Reference:

Hip Joint, Metal/Polymer, Semi-
Constrained, Cemented Prosthesis
21 CFR §888.3350

Predicate Device Identification

The Osteonics® Offset Hip Stems are substantially equivalent to the following competitive and/or Osteonics devices, which have previously been determined substantially equivalent by FDA:

- Osteonics® Omnifit® Plus Cemented Hip Stems - Osteonics Corp.
- Osteonics® ODC Hip Stems - Osteonics Corp.
- Osteonics® Restoration Cemented Hip Stems - Osteonics Corp.

Device Description

The Osteonics® Offset Hip Stems are intended to be placed within the prepared femurs of patients requiring total or hemi- hip arthroplasty. These hip stems may be implanted either with or without the use of bone cement. The Osteonics® Offset Hip Stems are forged from cobalt chromium alloy, and are characterized by proportional stem sizing, proximal projected area, proximal grit-blasting, Osteonics® C-Taper femoral neck, enhanced offset, and a 127° neck angle. The stems are available in collared and collarless versions, and in a full range of sizes.

Intended Use:

The Osteonics® Offset Hip Stems are intended for single use in patients requiring either a Total Hip Replacement or a Hemi- or Bipolar Hip Replacement. The Osteonics® Offset Hip Stems are intended to be implanted in cemented or cementless applications.

The specific intended uses of the Osteonics® Offset Hip Stems include the following:

Indications**For use as a Bipolar or Hemi-Hip Replacement:**

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other considerations for use as a Bipolar or Hemi-Hip Replacement:

- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

For use as a Total Hip Replacement:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Statement of Technological Comparison:

The subject devices, essentially, are the predicate Osteonics® ODC Femoral Stems from the collar area down (except that the subject devices are made from forged rather than from cast CoCr alloy), and the predicate Osteonics® Omnifit® Plus Cemented Hip Stems from the collar area up. A more detailed comparison between the subject and predicate devices, in terms of design, materials and intended uses, follows.

Design:

As previously stated, the subject devices are nearly identical in design - from the collar area and up - to the predicate Osteonics® Omnifit® Plus Cemented Hip Stems. Both hip stem series feature Osteonics® C-Taper neck, a 127° neck angle, and extended head offsets.

Distal to the collar location, the subject hip stems are identical in design to the predicate Osteonics® ODC Femoral Stems. Both the subject and the predicate hip stem series are grit-blasted proximally (but distal to the collar). Both the predicate and the subject hip stem series share the same dimensions distal to the collar location. Both hip stem series feature a distal hole for use with an optional cement spacer.

Materials:

The subject devices, like the predicate Osteonics® Omnifit® Plus Cemented Hip Stems, are forged from ASTM F-799 cobalt chromium alloy.

Intended Use:

The subject devices share the same indications for use as one or more of the predicate devices identified above. In addition, both the subject devices and the predicate Osteonics® ODC Hip Stems are intended for cemented and cementless indications.

Performance Data:

Comparison of the subject hip stem series with a predicate hip stem series demonstrated that fatigue testing results for the predicate hip stem series can be relied upon to qualify the performance characteristics of the subject hip stem series.

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